

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 NORTH MARKET STREET  
P.O. BOX 1347  
WILMINGTON, DELAWARE 19899-1347

302 658 9200  
302 658 3989 FAX

MEGAN E. DELLINGER  
(302) 351-9366  
mdellinger@morrisnichols.com

May 8, 2024

The Honorable Jennifer L. Hall  
United States District Court  
for the District of Delaware  
844 North King Street  
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*;  
C.A. No. 21-1015 (JLH)

Dear Judge Hall:

We write on behalf of Sarepta Therapeutics, Inc. and the University of Western Australia (“Sarepta”) in response to yesterday’s Order (D.I. 566) and NS’s letter of late last night (D.I. 569).

**Claim Construction:** NS spends nearly three pages of its letter repeating exactly the same arguments it made at Monday’s Pretrial Conference, despite Your Honor’s instruction that you fully understood both parties’ claim construction positions and only wanted to know whether the case can move forward next week. D.I. 570 at 80:9-82:19. As such, Sarepta will not rehash its arguments here, other than to stress that its asserted claim clearly requires that the antisense oligonucleotide (ASO) of 20-31 bases is 100% complementary *throughout its entire length* to consecutive bases of a target region of exon 53, for the reasons set forth in Sarepta’s claim construction briefs. D.I. 166 at 8-13, 15-17, 30-37. Any other construction would contradict the plain language of the claims, the teachings of the specification, and the scientific literature. *Id.*; see also D.I. 570 at 58:23-61:20, 76:1-16; D.I. 427-5 at ¶45 (NS’s expert admitting NS’s proposed construction renders the “100% complementary” limitation superfluous).

**Trial Timing:** NS represents that it is unprepared to go to trial if the Court adopts Sarepta’s proposed construction. D.I. 569 at 3. Although Sarepta remains ready and willing to go to trial

The Honorable Jennifer L. Hall  
May 8, 2024

next week, it does not object to a continuance for NS to amend its expert reports to take into account a revised construction.<sup>1</sup> If so, the case should be trial-ready by Q3 2024.

**Multiple jury trials:** Sarepta strongly disagrees with NS's proposal of a trial next week on NS's patents alone. That would give NS an unfair advantage, by telling the jury only half the story. It would be especially unfair here where both sides have already been found to infringe each other's patents, both allege willfulness, and NS's purported inventors literally started their exon 53 project by studying Dr. Wilton's patent application, then used it as a benchmark throughout the remainder of their work. The jury should have the complete picture, not a one-sided presentation.

More importantly, splitting one jury trial into two would be a tremendous waste of resources. The competing claims involve the same technology (exon 53-skipping ASOs for treating Duchenne muscular dystrophy (DMD)), identical expert witnesses (all *seven* experts opine on issues relevant to both NS's and Sarepta's patent claims), nearly identical fact witnesses (all three Sarepta fact witnesses would likely testify in both trials, and the same likely goes for multiple NS fact witnesses), and extensive overlapping evidence. Moreover, Dr. Wilton's (Sarepta's) seminal patent application was filed six years before NS's, making it a key part of the background and state of the art for NS's patent claims as well. The subject matter, witnesses, and evidence are so overlapping that holding two trials (including selecting and instructing two juries, educating both juries on DMD and ASOs, and the like) would require nearly double the time, wasting the Court's valuable resources, and requiring twice as many Delaware citizens to sit through similar trials involving the same complex technology with the same witnesses. What's more, NS has no reasonable justification for rushing to trial ahead of Sarepta, since neither is seeking an injunction, and NS can be made whole for any liability with damages if the jury so determines. In short, there is no justification to divide these highly-overlapping claims into two trials in front of two juries.<sup>2</sup>

**Additional briefing:** Finally, additional claim construction briefing and argument is unnecessary because (1) this issue has already been fully briefed, (2) the Court has already studied those briefs and fully understands the parties' positions (D.I. 570 at 80:9-14), and (3) NS already presented a slide deck and argument at Monday's Pretrial Conference.

We are prepared to discuss these issues on tomorrow's telephone conference, or earlier if the Court prefers.

---

<sup>1</sup> NS's supplemental reports (and Sarepta's responsive reports) should be limited solely to issues implicated by the revised construction (*i.e.*, NS could not use it as an excuse to proffer new arguments that would have been equally applicable under the prior construction).

<sup>2</sup> NS asks for a bench trial next week on its breach of contract claim even if the jury trial is continued because one of its witnesses and his interpreter are already in Wilmington. (D.I. 569 at 4.) That request should be denied because (1) that witness (Mr. Toda) is also on NS's jury trial "will call" list, so will need to return for the jury trial in any event and (2) that claim is for a tiny fraction compared to the patent damages claims, so should be amenable to resolution without need for trial. D.I. 570 at 83:12-25.

The Honorable Jennifer L. Hall  
May 8, 2024

Respectfully,

*/s/ Megan E. Dellinger*

Megan E. Dellinger (#5739)

cc: All Counsel of Record (via CM/ECF and e-mail)